NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

October 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

The National Hemophilia Foundation (NHF) would like to take the opportunity to comment on the recently published FDA document entitled "Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products." In his statement before the Aug. 27, 1998, meeting of the Blood Safety and Availability Committee meeting, Surgeon General David Satcher, M.D., PhD stated "if we are to err, then we will err on the side of safety." The NHF applauds this stance and believes that many of the key proposals put forth in this guidance document are consistent with this philosophy.

With respect to the transmission of classical CJD through blood and plasma derivatives, the NHF agrees that the epidemiological data and the results of studies on the partitioning of TSE agents during plasma fractionation are becoming increasingly reassuring. Nonetheless, the NHF is in agreement with the FDA's position that potential blood donors diagnosed with CJD or with CJD risk factors should be deferred and that blood components collected from such donors should not be used in the manufacturing of injectable products.

In contrast to CJD, there is at present a critical lack of long term epidemiological data pertaining to nvCJD. Moreover, known differences in the biology of the two diseases, particularly the predilection of the infectious agent of nvCJD for lymphoid tissue, are particularly worrisome when considering the potential of this agent to be transmitted by blood products. For these reasons, the NHF supports the deferral of donors diagnosed with, or at higher risk for nvCJD. Similarly, the NHF agrees with proposed guidelines promulgating the withdrawal of pooled plasma and its derivatives from donors subsequently diagnosed with nvCJD or found to be at higher risk for this disease and believes that this policy should include patients clinically diagnosed with "suspected" nvCJD in cases where neuro-pathological specimens are unavailable.

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The NHF recognizes that the deferral of individuals who have spent a cumulative period of six months or more in the United Kingdom since 1980 remains particularly controversial. However, it is important to note that nvCJD represents a new disease for which there remains a very high degree of uncertainty about the eventual scope of the epidemic. The proposed guidelines reflect the recommendations of the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) which were subsequently endorsed by the HHS Blood Safety Committee. According to an American Red Cross survey, in some parts of the U.S., as many as 30% of current U.S. blood donors have visited the U.K or Ireland. However, most of these trips were of short duration and would be predicted to result in minimal, if any, exposure to BSE. Adoption of a six-month exposure period for donor deferral has been predicted to result in only a 2-3% loss from the current blood donor pool. In considering this question, the TSE attempted to minimize the potential impact to the U.S. blood supply while retaining most of the theoretical benefit of increased safety. The NHF believes that the proposed guidance achieves the correct balance in these two objectives.

The NHF believes that patients who inadvertently receive CJD- or nvCJD-implicated products should be so informed and appropriately counseled. We therefore support the proposed guidelines to that effect and advocate that product tracing and notification should be extended to all affected recipients. The NHF also supports the labeling of non-implicated products with respect to the theoretical risks of TSE transmission.

Although the NHF is mindful of the potential impact of the proposed guidelines on the availability of blood products, we believe that such measures are highly appropriate and will serve to better assure the future health of the intended recipients of these products. The bleeding disorders community has learned much from the painful experiences of the 1980's when similar debates took place in which the impact of supply and cost were weighed against the then theoretical risks of the transmissibility of HIV and hepatitis through blood and blood products. The NHF recognizes that there is at present no conclusive evidence that the infectious agents of CJD or nvCJD can be similarly transmitted by this route. However, prion disease has been experimentally transmitted in this manner in animals and the research is ongoing. The NHF very much encourages this research and is fully prepared to modify our current recommendations based on the conclusions of these studies.

Again, thank you for allowing the NHF the opportunity to comment on this new guidance document.

Sincerely,

Bruce Ewenstein

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